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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/522,030	03/09/2000	James A Thomson	96-0296-96544	4331

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EXAMINER
WOITACH, JOSEPH T

ART UNIT	PAPER NUMBER
1632	24

DATE MAILED: 08/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

File

Office Action Summary	Application No.	Applicant(s)	
	09/522,030	THOMSON, JAMES A	
	Examiner	Art Unit	
	Joseph T Woitach	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *27 May 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *1-14 and 17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1-14 and 17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *19* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

This application is an original application filed March 9, 2000.

Applicant's amendment filed May 27, 2003, paper number 23, has been received and entered. Claims 1, 9, 14 and 17 have been amended. Claims 1-14, and 17 are pending and currently under examination.

Response to Amendment

The declaration of Dr. Thomson filed March 25, 2003, paper number 20, is found persuasive with respect to the ability of forms of FGF other than bFGF to function within the instantly claimed methods (sections 2-4). With respect to the ability of other factors such as LIF to function in a similar fashion when serum replacement is used (section 5) the statements provide further evidence that the growth effect on primate cells is due to FGF.

Information Disclosure Statement

It is noted that the Ornitz *et al.* reference has been provided as an attachment to the declaration of Dr. Thomson filed March 25, 2003, paper number 20. However, it has not been listed in a new IDS and thus fails to comply with 37 CFR 1.98(a)(1), which requires a list of all patents, publications, or other information submitted for consideration by the Office. It has been

placed in the application file, but the information referred to therein may not have been completely considered.

Specification

As noted in the previous office actions, the use of the trademark KNOCKOUT SR has been noted in this application (page 6; line 22). It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-14 and 17 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Hogan *et al.* ('372), Hogan *et al.* ('926) and Goldsborough *et al.* (FOCUS 20(1):8-12, 1998).

Applicant notes the amendments to the claims and maintains that the claimed invention is non-obvious and fully enabled as presently set forth. Applicant notes that in the advisory action mailed December 18, 2002, paper number 13, Examiner indicated that the use of bFGF provided an unexpected synergistic affect when used to culture primate cells. Further, in light of the declaration of Dr. Thomson and the teaching of Ornitz et al. one of skill in the art would expect that other forms of FGF would have a similar unexpected affect. See Applicant's amendment, pages 4-5. Applicant's arguments have been fully considered, but not found persuasive.

Initially, as indicated in the advisory action Examiner would agree that the addition of basic FGF to Knockout D-MEM media provides a specific condition that would not have been expected by the cited references. However, the claims are broader than this embodiment and encompass the use of any FGF or simply activating the FGF receptor and in any serum free condition. The amendment to the claims to include components which are in serum replacement medias is noted however, there is insufficient information in the present specification or the declaration to determine whether these are the factors or which factors act synergistically with bFGF to provide for an unexpected result in view of the art as a whole. The courts have held that consistent with the rule that all evidence of nonobviousness must be considered when assessing patentability, the PTO must consider comparative data in the specification in determining whether the claimed invention provides unexpected results. See *In re Margolis*, 785 F.2d 1029, 1031, 228 USPQ 940, 941-42 (Fed. Cir. 1986). Importantly, in this case it is also well established that the evidence presented to rebut a *prima facie* case of obviousness must be

commensurate in scope with the claims to which it pertains. See *In re Dill*, 604 F.2d 1356, 1361, 202 USPQ 805, 808 (CCPA 1979). Therefore, while the evidence in the instant specification provides support for an unexpected effect of basic FGF in culturing primate cells with Kockout D-MEM media for providing the specific serum free conditions, the instant claims encompass any serum free culture condition and any FGF or affecting the FGF receptor.

Therefore, because of the breadth of the instant claims it is maintained that the claimed methods would be obvious over the teachings of Hogan *et al.*, Hogan *et al.* and Goldsborough *et al.* The test for combining references is not what the individual references themselves suggest, but rather what the combination of disclosures taken as a whole would have suggested to one of ordinary skill in the art. *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). Further, the courts have maintained that obviousness does not require absolute predictability of success; for obviousness under 35 U.S.C. § 103, all that is required is a reasonable expectation of success. See *In re O'Farrell*, 7 USPQ2d 1673 (CAFC 1988). In the instant case, the example of LIF having no affect on primate cells is not unexpected in light of the differences between mouse and primate embryonic stem cells already known and described in the art. Given the breadth of the instantly claimed methods, there was a reasonable teaching and expectation that the addition of growth factors, in particular the family of FGFs would be necessary in the optimization of growth conditions for embryonic stem cells, and that the addition of these factors would result in better culturing conditions.

Therefore, for the reasons above and of record, the rejection is maintained.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (703)305-3732.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at (703)305-4051.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (703) 308-2141.

Joseph T. Woitach

Deborah Crouch

DEBORAH CROUCH
PRIMARY EXAMINER
GROUP ~~1800~~ 1630